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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
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09/150,947    09/10/98    KAEMPFER    R    A31967-PCT-U

BAKER & BOTTS  
30 ROCKEFELLER PLAZA  
NEW YORK NY 10112-0228

HM22/1002

EXAMINER

LEE, L

ART UNIT

PAPER NUMBER

1645

14

DATE MAILED:

10/02/00

**Please find below and/or attached an Office communication concerning this application or proceeding.**

**Commissioner of Patents and Trademarks**

# Office Action Summary

Application No.  
09/150,947

Applicant(s)

Kaempfer et al

Examiner

LI Lee

Group Art Unit  
1645



☒ Responsive to communication(s) filed on Apr 24, 2000

☐ This action is **FINAL**.

☐ Since this application is in condition for allowance except for formal matters, **prosecution as to the merits is closed** in accordance with the practice under *Ex parte Quayle*, 1035 C.D. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire 3 month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

## Disposition of Claim

☒ Claim(s) 50-84 is/are pending in the application

Of the above, claim(s) \_\_\_\_\_ is/are withdrawn from consideration

☐ Claim(s) \_\_\_\_\_ is/are allowed.

☒ Claim(s) 50-84 is/are rejected.

☐ Claim(s) \_\_\_\_\_ is/are objected to.

☐ Claims \_\_\_\_\_ are subject to restriction or election requirement.

## Application Papers

☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

☐ The drawing(s) filed on \_\_\_\_\_ is/are objected to by the Examiner.

☐ The proposed drawing correction, filed on \_\_\_\_\_ is ☐ approved ☐ disapproved.

☐ The specification is objected to by the Examiner.

☐ The oath or declaration is objected to by the Examiner.

## Priority under 35 U.S.C. § 119

☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

☐ All ☐ Some\* ☒ None of the CERTIFIED copies of the priority documents have been

☐ received.

☐ received in Application No. (Series Code/Serial Number) \_\_\_\_\_

☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

\*Certified copies not received: \_\_\_\_\_

☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

## Attachment(s)

☒ Notice of References Cited, PTO-892

☐ Information Disclosure Statement(s), PTO-1449, Paper No(s). \_\_\_\_\_

☐ Interview Summary, PTO-413

☐ Notice of Draftsperson's Patent Drawing Review, PTO-948

☐ Notice of Informal Patent Application, PTO-152

— SEE OFFICE ACTION ON THE FOLLOWING PAGES —

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### DETAILED ACTION

1. Applicant's amendment filed on Mar 15, 2000 (Paper Number 9) has been received and entered. Claims 1-49 have been canceled, and new claims 50-84 have been added, consequently claims 50-84 are pending in the instant application.
2. The abstract of the disclosure is objected to because it contains more than one paragraph is withdrawn in view of applicant's new abstract.
8. The rejection of claims 1-33 under 35 U.S.C. 112, second paragraph, as being indefinite for using the term "substantially homologous" is maintained and applied to newly added claims 50-64 and 76-84 for the reasons set forth in the office action mailed on 9/14/99 and below.
3. In response to applicant's argument that the specification discusses sequence homologies among related pyrogenic toxins on page 26 and the meaning of "substantial homology" can be ascertained by the disclosure that related exotoxin proteins share between 9/12-10/12 amino acid residues with SEB in the region of amino acids 150-161 of SEB, it is noted that the features upon which applicant relies are not recited in the rejected claim(s). Although the claims are interpreted in light of the specification, limitations from the specification are not read into the claims. See *In re Van Geuns*, 988 F.2d 1181, 26 USPQ2d 1057 (Fed. Cir. 1993).
4. The rejection of claims 1-8, 13-16, 18, 21, 23, 26-30 under 35 U.S.C. 102(b) as being anticipated by Tseng et al (Infection and Immunity 63 (8):2880-2885, Aug 1995) is maintained and applied to the newly added claims 50-84 for reasons set forth in the office action mailed on 9/14/99 and below.

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The claims 50-84 are drawn to an isolated peptide having an amino acid sequence substantially homologous to an amino acid sequence of a domain of a pyrogenic exotoxin and the derivatives of the peptide.

In response to applicant's argument that the references fail to show certain features of applicant's invention, it is noted that the features upon which applicant relies (i.e., isolated peptide derived from, but do not constitute a full length toxin protein) are not recited in the rejected claim(s). Although the claims are interpreted in light of the specification, limitations from the specification are not read into the claims. See *In re Van Geuns*, 988 F.2d 1181, 26 USPQ2d 1057 (Fed. Cir. 1993). Moreover the claims 50-84 are drawn to isolated peptide and the derivatives with open language, encompass a full length toxin protein. In order to advance the prosecution in light of the rejections above under 35 U.S.C. 112 second paragraph, claims 50-84 are interpreted by the examiner to read on the derivatives of the isolated peptide, which are derived in any ways from the isolated peptide (e.g., synthesized from single amino acids derived from the peptides). Therefore, the peptide of Tseng et al anticipates the derivatives from peptides of SEQ ID Nos:1-12 because they are all peptides derived from pyrogenic exotoxin having amino acid sequences of SEQ ID NO:1-12 and the peptide of Tseng et al exhibit substantial homology to the peptides of SEQ ID NO:1-12. Moreover, the peptide of Tseng has the same activity as the claimed peptide, such as being capable of eliciting protective immunity against toxic shock induced by a pyrogenic exotoxin and by a mixture of pyrogenic exotoxins, and capable of inhibiting expression of pyrogenic toxin-induced mRNA encoded by the IL-2, IFN- $\gamma$  or TNF- $\beta$

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genes, capable of eliciting the production of antibodies that block T-cell activation, and capable of antagonizing toxin-mediated activation of T cells.

*New Grounds of Rejections*

*Claim Rejections - 35 USC § 112*

5. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

6. Claims 50-84 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 50-84 are indefinite for using the term "derivatives". It is not clearly defined the way the peptides are derived. Without clearly defining the way the peptides are derived, one of ordinary skill in the art cannot determine the metes and the bounds of the claimed invention.

Claims 50, 52-64 and 76-84 are indefinite as there is no defined specific peptide sequence for the amino acid sequence of a domain of a pyrogenic exotoxin in the claims. Without reciting a specific amino acid sequence for the domain of the toxin, one cannot compare the homology between the claimed peptide and the amino acid sequence of a domain of a pyrogenic exotoxin. Without such information, one of ordinary skill in the art would not be reasonably apprised of the

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metes and bounds of the claimed subject matter. Claims 50, 52-64 and 76-84 are further indefinite for using the term "connecting it" in claim 50. It is not clear what limitation is implied by the recitation of "connecting it". Such might indicate that "it" is the domain of a pyrogenic exotoxin, or alternatively might be indented to indicate that "it" is T lymphocytes or MHC II molecules.

***Claim Rejections - 35 USC § 102***

7. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless --

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

8. Claims 50-84 are rejected under 35 U.S.C. 102(e) as being anticipated by Dow et al (US 5,705,151, Jan 6, 1998).

Dow et al teach an isolated peptide having a amino acid sequence (SEQ ID NO:2) 99.8% identical to the claimed amino acid sequence of SEQ ID NO:12, which is completely identical to the claimed N-terminal and C-terminal structures.

The peptide of Dow is capable of antagonizing toxin-mediated activation of T lymphocytes (column 3-4, lines 49-55). The peptide of Dow is the <sup>same as</sup> derivatives of the peptides from pyrogenic

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exotoxin having amino acid sequences of SEQ ID NO:1-12 and the peptide of Dow et al is substantially homologous to any one of the peptides of SEQ ID NO:1-12.

*Status of Claims*

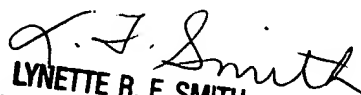
9. No claims are allowed. All claims stand rejected.

Any inquiry of a general nature or relating to the status of this general application should be directed to the Group receptionist whose telephone number is (703) 308-0196.

Papers relating to this application may be submitted to Technology Center 1600, Group 1645 by facsimile transmission. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989). Should applicant wish to FAX a response, the current FAX number for Group 1600 is (703) 308-4242.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Li Lee whose telephone number is (703) 308-8891. The examiner can normally be reached on Monday-Friday from 8:30 AM to 5:00 PM. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Lynette Smith, can be reached at (703) 308-3909.

Li Lee  
September 28, 2000

  
LYNETTE R. F. SMITH  
SUPERVISORY PATENT EXAMINER  
TECHNOLOGY CENTER 1600